REMARKS

1. Presently claims 1, 2, 4, 9 to 10, 12, and 15 are under examination. Claim 14 was incorporated into claim 4 and is thus now cancelled.

2. The Examiner has rejected claims 1, 2, 4, 12 and 14 under 35 U.S.C. §103(a) as being unpatentable over Wolff ('554) for the reasons noted in paragraph 3.

Applicant's prior traverses are incorporated by reference.

The *prima facie* case of obviousness has not been established with respect to Wolff because the reference does not suggest, teach, or imply the motivation to combine or modify the reference teachings in order to produce the present invention. Moreover, the reference does not disclose all of the elements of the present invention as set out in the claims. In sum, the present invention is not obvious in view of Wolff because Wolff fails to suggest the desirability of using coherent radiation and optical fibers to stimulate the physical healing of stage 1 and stage 2 wounds, and, in particular, using a 980 nm wavelength.

The Examiner notes that Wolff discloses the use of electromagnetic radiation for the treatment of acne, psoriasis, etc. (Col. 1, lines 49-57)

Wolff minimally discloses the treatment of the body for psoriasis, acne and other skin irregularities or diseases with UVA radiation in the range from about 315 to 400 nm. Col. 1, lines 20 to 28, and 50 to 55 being in the Background. As to the treatment of psoriasis and acne, Wolff notes that the prior apparatus filtered out radiation in the range of 300 to 315 nm " but that this is most effective for these purposes." Col. 1, lines 53 to 57.

The Examiner states at the bottom of page 2, "it would have been an obvious matter of design choice to a person of ordinary skill in the art to utilize such an arrangement because the applicant has not disclosed that coherent light applied with an optical fiber provides an advantage, is used for a particular purpose, or solves a stated problem."

The Examiner's attention is directed to U.S. Patent 6,165,205, issued December 26, 2000, to the same assignee, but is directed at wound healing where "complicating factors are present." Col. 2, lines 46. The type of wound being treated by the '205 patent is further disclosed where "the laser therapy can be preceded by mechanically scraping the surface of the wound to remove necrotic tissue." This is clearly not the same wound stage as covered by the

present invention being Stage 1 or 2, but is directed at Stage 3 or Stage 4 wounds. See page 1, lines 9 to 15, of that patent.

The benefit of the present invention of the use of the optical fiber is noted as "to radiate the wound's surface from a distance of several millimeters. The fibers and/or the radiation spot may be manually moved over the surface of the wound or a scanner may be employed to evenly irradiate the wound site." As to the particular purpose of the optical fibers, "Possible delivery means include, , bare fibers, ..." Page 6, line 24. Further, the optical fiber may be in very close proximity to the wound to increase the power density and limit the area of application. Page 7, lines 19 to 26. This is clearly different than the use of tanning lamps, which broadly emit their rays.

As to whether non-coherent radiation is appropriate is not an issue since this was deleted from claim 1.

The Examiner states, on page 3, the "healing process is clearly not dependent upon the particular means used to transmit the radiation to the wound-" If this were so, then the patient could just sit outside in the sun or under a sun lamp or an arc lamp, but as noted above, in order to achieve appropriate energy levels as well as energy densities at the wound itself, an optical fiber is used. No other cited reference discloses the benefits of using a laser source and an optical fiber, in combination, and further the benefits of using, in particular, 980 nm coherent radiation. Talmore uses an arc lamp that delivers a power density of 17.3 mW/cm^2 through the use of a large diameter light guide whereas the present invention delivers a power density of 5.29 W/cm^2 which is significantly higher through one or more fibers having a diameter of approximately 100s nm. This provides a power density of several hundred times, that is more than 2 orders of magnitude greater than the suggested reference,

It is certainly not clear how logic and sound scientific reasoning would have led one of ordinary skill in the art to make the claimed invention, MPEP 2144.02, since the most relevant patent is owned by the same assignee and can not be used in the 103 rejection since the present application was filed within the one year of issue. Talmore does not use an optical fiber per se but a light guide having a diameter from about 2 to 10 mm which far exceeds the diameter of the fibers used in the present invention. Again very high powers would have be available to reach

the power densities employed in the present invention since the light guides are 100 to 2500 times larger in area than the typical fibers used in the present invention.

Therefore, the features of the present invention are not mere design choices and are not obvious in light of any artisan looking to direct the radiation. These are significantly different parameter ranges, well beyond simple trial and error minor experimentation.

As to the treatment of Stage 1 or Stage 2 wounds, it is obvious that a person would try to treat a Stage 1 or Stage 2 wound to prevent its progression into Stage 3 or 4, but the issue is not that desire but whether that treatment would be effective in preventing the progression of the wound. The preamble of claim 1 establishes the goal of the present invention. It is certainly not true that psoriasis and eczema will not progress to higher stages if not treated properly even though as stated by the Examiner, "Psoriasis is psoriasis regardless of the stage it is in." is a true statement as to any disease from cancer to a common cold, but once the disease is identified, it typically has different stages of progression, danger to the patient, and the treatment at each stage would generally be different also. For example, the early treatment of basal cell skin cancer may be merely freezing it, but the later stage may require chemotherapy or radiation treatment to try to kill cancer cells that have migrated into the body from the skin surface. Anyone skilled in the art of medical treatments would realize, that one does not treat a wound where there is necrotic tissue, the same as one does where it merely appears to be a sun burn. The issue is whether the treatment will prevent progression and healing of the early stage wounds as presented in the present application.

U.S. Patent 6,15,205, being assigned to the present assignee, is directed at the treatment of wounds that have progressed beyond the Stage 2; for example, where there is a need for production of fibroblasts, synthesis of collagen and removal of dead tissue and fibrin.

The Examiner states as to claim 2, "the power density of the Wolff device to be at least 1 W/cm^2 ..." A review of this patent finds no such device, the examples are all in the range of 10 mW/cm^2, that is over two orders of magnitude lower than the present invention. In most medical applications this is very significantly different.

Again, applicant has amended Claim 4 as noted above and added new Claim 15 which is directed at laser radiation of the 980 nm wavelength which is clearly outside the range of wavelengths noted and preferred by Wolff. See Col. 1, lines 58 to 67. Col. 3, lines 47 to 62. Wolff notes that the source of radiation is a non-laser source, Col. 2, lines 65 to 67, and it is therefore noncoherent. See Whitehurst where 100 mW/cm2 is taught; 50 to 500 times of magnitude smaller than in the present invention.

The Examiner states as to Wolff, "skin disorders such as acne and psoriasis may be effectively treated; the power density must be of a sufficient magnitude in order for any beneficial results to occur." This is totally descriptive, with little direction or guidelines to not require extensive experimentation.

The effective treatment depends on the Stage of the wound, to be treated, and following that the power density must be adjusted accordingly. Just because psoriasis is claimed to be psoriasis by the Examiner does not mean that only one power density is required for an effective treatment. The devices illustrated by Wolff certainly do not lend themselves to high power densities and are nothing more than tanning lamps. See Col. 6, lines 1 to 8, indicating a wavelength of 300 to 315 nm to pass from the lamps. See also Col. 11, lines 21 to 28, noting a wavelength of from 300 to 315 nm for medical treatment. It is thus clear from the disclosure in Wolff that a power density cannot be obtained for the treatment of wounds with the devices of Wolff that are meant for tanning. Wolff only discloses lamp device whereas the present invention involves laser radiation applied by means of one or more optical fibers.

As to claim 12, Wolf does not disclose the removal of bacteria, etc., from the wounds. It is unclear why the treatment of psoriasis by Wolff would also eliminate bacteria and the Examiner has presented no evidence of such elimination. See MPEP 2144.02. One might guess the use of ultraviolet light would help do this, but then the wavelength region and use of coherent light are further non-obvious aspects of the present invention.

As to claim 15, the Examiner claims that the choice of wavelength is based on experimentation and that the "applicant further gives no critically to the use of 930(sic) [should be 980 nm] nm radiation. ... provides an advantage, is used for a particular purpose, or solves a stated problem."

The applicant notes that on page 3, lines 14 to 19, "it has been shown that irradiation of an open wound with a 980 nm laser at powers of at least 5 Watts, continuously applied for a period between 10 seconds and 20 minutes or greater, is an effective method of stimulating the healing of open wounds." Reference is made to U.S. Patent 6,165,205, being assigned to present assignee, and thus shows the state of the art as applied to the present invention by the inventor who works for the assignee.

It has been found that 980 nm laser radiation is effective for numerous medical procedures and treatments by the assignee. The applicant states on page 7, line 5 to 8, "the present method is equally effective for and particularly beneficial to diabetics and other patients with conditions that would normally either inhibit wound healing or accelerate the progression of a wound to stage 3 or stage 4."

The examples shown in the present application specifically disclose the use of 980 nm laser radiation applied by optical fiber and having a power density of about 5 to 45 W/cm^2.

It is therefore can be asserted that the specifications does identify 980 nm and Wolff does not make obvious the present invention, because of significantly different levels of power density employed and type of light energy as well.

3. The Examiner rejected claims 1, 2, 4, 12, 14 and 15 under 35 U.S.C. 103(a) as being unpatentable over Whitehurst for the reasons noted.

Applicant's prior traverse is incorporated by reference.

Applicant had previously amended Claim 1 to include therein the prior dependent claim directed at the radiation being coherent. New Claim 15 is directed at the coherent radiation being laser radiation of the particular wavelength that was disclosed in the Examples.

The Whitehurst reference is totally directed at an incoherent high intensity non-laser source. See Col. 1, lines 10 to 31. The applicable wavelength of this reference is shown on Figures 2b and 2c having a wavelength centered on 630 nm as contrasted to the present invention of 980 nm. Further, the intensity is noted as 100 mW/cm^2 when output by the optical fiber of Whitehurst as contrasted to the present invention where a power density of at

least about 1 W/cm^2, claim 2. An intensity of up to 9 W/cm^2 is noted but being focused. Col. 3, lines 54 to 55.

Thus, unlike the present invention, Whitehurst does not teach or suggest a light source that prevents wound progression or enhances healing of stage 1 or stage 2 wounds.

The Examiner claims that "those of ordinary skill in the art would have considered the use of a coherent light source such as a laser to be obvious for the healing of stage one and stage two wounds." Page 4.

Why it is obvious to one skilled in the art is not made known by the Examiner. See MPEP 2144.02. Since prior to this application the ability/safety let alone need for modestly high power densities to treat wounds is not discussed; mere hypothetical examples are not appropriate. In fact the real world has not found it so obvious, as prior to the present invention no studies have described such use at the levels claimed herein. One knowing the increased power generally of coherent light over non-coherent would certainly not have thought that increased power density for a 'stronger light source' would be the way to safely and effectively treat minor wounds, i.e. stage 1 and 2 wounds. In fact generally people were talking of low to very low intensity light irradiations to effect minor wound healing. The levels taught in the present invention would have been judged unsafe and tremendous overkills.

4. The Examiner rejected claims 9 and 10 under 35 U.S.C. 103(a) as being unpatentable over Whitehurst as applied to claims 1, 2, 4, 12, 14 and 15, and further in view of Talmore for the reasons noted on page 5.

The Examiner claims that on page 5, "Whitehurst does not appear to explicitly discuss the average power of the radiation energy produced by the 200 W Xenon short arc lamp."

On Col. 4, lines 33 to 40, of Talmore, the energy density delivered by the light guide is noted as 17.3 mW/cm^2 which is significantly less than that claimed in the present invention. The 1 W output is only noted in the range from 330 to 370 nm which is well below the 980 nm operating wavelength of the present invention and is clearly less than the delivered output to the skin as noted in the present invention.

The Examiner claims, "Lacking any critically by the applicant in regards to providing a 1 W output or a 5 to 10 W output, those of ordinary skill in the art would have seen the particular power level to be an obvious matter of design dependent upon the conditions of the particular wound being treated."

Applicant again notes that no references have been produced to support such a conclusion and points to U.S Patent 6,165,205, being commonly assigned, and directed at wound healing of Stage 3 and Stage 4 wounds wherein such power levels were used to treat Stage 3 or Stage 4 wounds. Though using equally high energy levels for much less significant wounds would generally run counter to human experience.

The amount of energy needed to treat Stage 1 and Stage 2 wounds has not been disclosed except in the present invention.

In view of the unpredictability of tissue-light interactions and the differences between various wound types, there is no reasonable expectation of success that results from combining the teachings of Whitehurst and Talmore. Without a reasonable expectation of success, the present invention is not made obvious by Whitehurst in view of Talmore.

5. The Examiner rejected claims 9 and 10 under 35 U.S.C. 103(a) as being unpatentable over Whitehurst as applied to claims 1, 2, 4, 12, 14 and 15, and further in view of Talmore.

Prior traverses are incorporated by reference.

The 1 W of Talmore refers to a narrow beam of light, but Claims 9 and 10 are dependent off of claim 2 which notes a power density of 1 W/cm^2. But, following the above, Talmore specifically describes that the energy focused is 17.3 mW/cm^2. This is far less that the energy density claimed by the present invention. See Talmore Col. 4, lines 25 to 40. Talmore uses a light guide having a diameter of 5 mm which far exceeds the diameter of the conventional optical fiber used in the present invention to further assist in obtaining the power density applied. It is further noted that Talmore must direct light from the arc lamp into this light guide which results in the lower energy density. The present invention relies on a more direct coupling of the laser energy from a laser diode, for example, into an optical fiber.

Having an energy density 50 to 500 times higher, clearly provides novel and non-obvious operating parameters to effectively treat wounds, and especially if one realizes that operating at

980 nm has been shown to be highly effective in wound treatment (see patent '205 same assignee). As noted in Example 2, the power density is 44 Watts/cm^{2}and therefore the higher powered range is supported by the specification in the treatment of a rash.

With these changes and remarks, it is believed that the disclosure is now in condition for allowance and reconsideration is respectfully requested. An early and favorable response is earnestly solicited. Thank you.

Respectfully submitted,

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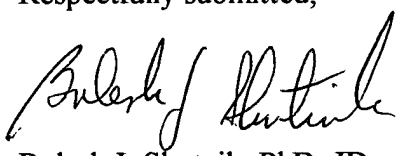

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